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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,421	07/30/2001	Akira Suyama	01450/HG	6390

1933 7590 01/27/2003

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,421	Applicant(s) SUYAMA, AKIRA	
	Examiner Channing S. Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 20 November 2002.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 6-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 6-12 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 Sheet</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____
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Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	09/918,421
				Filing Date	July 30, 2001
				First Named Inventor	Akira SUYAMA
				Group Art Unit	1631
				Examiner Name	MAHATAN
Sheet	1	of	1	Attorney Docket Number	01450/HG
OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
CSM ↓ ✓		BECKER ET AL: "Primer Design - A New Program to Choose PCR Primers and Oligonucleotide Probes", MEDIZINISCHE GENETIK, BERUFSVERBAND MEDIZINISCHE GENETIK, MUNCHEN, DE, Vol. 7, No. 2, (1995), pages A-158. HYNDMAN D. ET AL: "Software to Determine Optimal Oligonucleotide Sequences Based on Hybridization Simulation Data", <u>BIOTECHNIQUES</u> , Vol. 20, No. 6, (1996), pages 1090-1097. MITSUHASHI M. ET AL: "OLIGONUCLEOTIDE PROBE DESIGN - A NEW APPROACH", <u>NATURE</u> , MACMILLAN JOURNALS LTD., LONDON, GB, Vol. 367, February 24, 1994. pages 759-761.			
Examiner Signature	C. Mu H			Date Considered	Aug 29, 2003

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Place a check here if English translation is attached.

DATE MAILED: OCTOBER 23, 2002

DETAILED ACTION*APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 10, filed 20 November 2002, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Additionally, the *FIRST AND SECOND SPECIES ELECTION* set forth in Paper No. 3 was reconsidered and is now vacated on the grounds that such species are not patentably distinct.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 6-12.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the

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art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 6-12 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant claim 6, lines 20-23, state “each of the candidate sequences having a low occurrence frequency index based on a threshold value of the occurrence frequency index obtained from the second calculation step” which is found non-enabling. While it is acknowledged that the specification indicates “The candidate sequences are selected based on an appropriate threshold value of the index” (page 15, lines 12-13), however, absent from the specification and/or the second calculation step (claim 6, lines 13-18; refer to the below 112 2nd Paragraph Rejection) are procedures/steps for the calculation of the threshold value to base the low occurrence frequency upon. Without proper guidance, direction, or examples for the calculation of the threshold value one of skill in the art would be unable to select a single or plurality of candidate sequences, thus not enabled to practice the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 6 and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “A method of determining a nucleotide sequence of an analytical oligo nucleic acid”, however the claim recites a final step of “a second extraction step of selecting a single or a plurality of candidate sequences”. There is no indication that a nucleotide sequence is intended to be determined as recited in the preamble. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when a nucleotide sequence is determined.

Clarification of the metes and bounds of the claim is requested via clearer claim wording.

MISSING ESSENTIAL STEP

Claim 6 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. The omitted step is: prior to step (a) of claim 6 an input nucleotide sequence for which the following step (a) can perform the first calculation step.

LACK OF ANTECEDENT BASIS

Claim 6 (lines 3-5) recites the phrase “a low occurrence frequency index based on a threshold value of the occurrence frequency index obtained from the second calculation step”,

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lacks antecedent basis for threshold value. There is no indication in the second calculation step that a threshold value is obtained and thus lacks antecedent basis.

CONFLICT BETWEEN CLEAN VERSION OF CLAIMS AND MARKED UP VERSION

Applicants are to note that claim 8 (line 3; “structure”) and claim 9 (line 3; “stability as measured by a”) of the “clean version” of claims differ from that of the “marked up version” of claims. To further prosecution the “clean version” of claims was utilized for examination purposes.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *Jan 22, 2003*
Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1800~~
Art 1631